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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,197

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Don Fishbein

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8168

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COOPER & DUNHAM, LLP  
30 Rockefeller Plaza  
20th Floor  
NEW YORK, NY 10112

EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

06/11/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,197	<b>Applicant(s)</b> FISHBEIN, DON	
	<b>Examiner</b> ALICIA R. HUGHES	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 30-47 are pending and the subject of this Office Action. Claims 46 and 47 were inadvertently omitted by the Examiner in the immediate past Office Action but are incorporated herein and heretofore.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's arguments filed on 16 March 2009 have been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections – 35 U.S.C. §103***

Claims 30-40 and 42-47 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"].

The Applicant argues that the etiology of the weight loss sought to be treated is consequential rather than inconsequential, because the same impacts if a given treatment can

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promote weight gain. Applicant also argues that the relationship between weight loss and actual weight gain is not predictable on the sole basis of oxandrolone fostering an increase in appetite, based on the teachings found in Sheffield Moore et al. Applicant affably points out that there can only be weight gain if the amount of weight added exceeds the amount of weight being lost and argues that based on the teachings of the prior art, whether this takes place is not predictable. Applicant goes on further to state that “[r]egardless of whether the ‘functionality’ of oxandrolone is changed by etiology, it does not predictably follow that oxandrolone administration will cause weight gain.” Please see Applicant’s remarks at page 5, para. 1. The Examiner disagrees.

The teachings of Berger as articulated in other Office Actions are incorporated herein by reference in total.

Regardless of Applicant's assertions and rationale otherwise, Berger teaches that through the administration of oxandrolone, “[l]oss in muscle mass (wasting) is attenuated, and body weight can be more readily maintained in this manner ... *revers[ing] weight loss*” (Col. 2, lines 1-5; see also, the Example at Col. 7, lines 33-57 – Col. 8, lines 1-24)(emphasis added). The impact of reversing weight loss is attenuating weight gain.

As noted prior, Berger does not teach the use of anabolic steroids in the treatment of burns. However, Schaffer teaches that the use of topically or systemically applied drugs, such as anabolic steroids, “for ... healing processes of physically, chemically or physiologically induced tissue lesion, such as burns, ... accelerate the healing process of tissue injuries” (Col. 1, lines 10-19).

One of ordinary skill in the art would be motivated to combine the teachings of Berger and the teachings of Schaffer, because the patents teach overlapping subject matter, namely

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treatment using anabolic steroids. In light of the foregoing, and absent any evidence to the contrary, one would conclude that it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of oxandrolone, in the dosages and dosage forms disclosed in the present invention, would be an effective method for promoting weight gain after weight loss for one who experiences loss of lean body mass due to burn-induced trauma.

Claims 30 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as “Berger”] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as “Schaffer”] and in further view of U.S. Patent No. 5,434,146 [hereinafter referred to as “Labrie et al”].

Applicant argues essentially that since there is no teaching of the method of claim 30 in the combination of Berger and Schafer and the same is not cured by the teachings of Labie et al, a case of *prima facie* obviousness has not been established. The Examiner disagrees for the reasons made of record *supra* and in prior Office Actions and maintains that a *prima facie* case of obviousness indeed has been established.

The teachings of Berger, *supra* and as well, from this Office’s previous related applications are incorporated herein by reference. As noted prior, Berger does not teach the administration of oxandrolone in a sustained release formulation. As noted prior, Labrie et al teach the administration of certain anabolic steroids, including oxandrolone, in a sustained release formulation (Abstract; Col. 21, lines 17 and 61-68).

One of ordinary skill in the art would be motivated to combine the teachings of Berger and Schaffer with the teachings of Labrie et al., due to their overlapping subject matter, most notably anabolic steroids. In view of the foregoing and absent any express evidence to the

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contrary, it would have been prima facie obvious to one of ordinary skill in the art that the administration of an effective amount of oxandolone in sustained release formulations would be effective for promoting weight gain after weight loss resulting from burn-induced trauma in a patient.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/

Primary Examiner, Art Unit 1614